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# Newron Pharmaceuticals

Clinical trial update

## Encouraging efficacy data from evenamide trial

Pharma and biotech

**Newron has presented new efficacy data from its Phase II evenamide trial (study 014/015) at the CINP World Congress of Neuropsychopharmacology and the 2023 Congress of the Schizophrenia International Research Society. These data, from the first 100 patients at the one-year timepoint, indicate significant and clinically important results, with continuous improvements across the Positive and Negative Syndrome Scale (PANSS) and the Clinical Global Impression of Change (CGI-C), Severity of Illness (CGI-S) and Strauss-Carpenter Level of Functioning (LOF) efficacy scales. While we anticipate full one-year results from the evenamide extension trial (study 015) in Q124, the company plans to initiate a potentially pivotal multinational Phase III trial (study 003) in treatment-resistant schizophrenia (TRS) patients in H223, which in our view, represents an important catalyst.**

| Year end | Revenue (€m) | PBT* (€m) | EPS* (€) | DPS (€) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/21 | 5.76 | (14.12) | (0.79) | 0.0 | N/A | N/A |
| 12/22 | 6.09 | (16.99) | (0.95) | 0.0 | N/A | N/A |
| 12/23e | 6.46 | (17.11) | (0.96) | 0.0 | N/A | N/A |
| 12/24e | 6.85 | (22.27) | (1.25) | 0.0 | N/A | N/A |

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

The latest update from study 015 provides full efficacy data for 100 patients at the one-year timepoint, assessed by changes from baseline across the PANSS, CGI-C, CGI-S and LOF scales. We note that the primary objective of the study is to evaluate the safety and tolerability of evenamide (at three fixed doses of 7.5mg, 15mg and 30mg bid), with PANSS being the primary efficacy indicator. The results showed an increased reduction in the PANSS total score at all timepoints versus baseline, with a PANSS responder rate (defined as showing a >20% improvement) of 47%, a 3x increase from 16% at week six. The CGI-C scale measurements showed that 41% of patients were rated as 'much' or 'very much' improved versus baseline. CGI-S measurements showed improvements of 1.1 units versus baseline, with 29% of patients observing two or three category improvements.

Overall, 38% of patients met the threshold for being classified as 'super-responders' (described as a 'full responder' in a previous update from the company), defined by: a PANSS total score improvement of at least 20%; a CGI-C of at least 'much improved'; a CGI-S of an at least one point improvement and at most 'mildly ill'. This represents a 2.5x increase from week six, which in our view is supportive of evenamide as potentially the first add-on therapy for TRS patients.

As a reminder, the Phase II evenamide trial (study 014, six weeks and study 015, an extension study) is an international, randomised, open-label, rater-blinded assessment of evenamide (safety and efficacy) as an add-on to an antipsychotic (excluding clozapine) in patients with moderate to severe TRS. With the encouraging efficacy data to date, we anticipate that improvements in clinical benefit over a longer period (in line with the observed trend for the first 100 patients), and systematic differences between doses of evenamide, if observed, will become clearer with time. One-year data from the full 161-patient cohort in extension study 015 are expected in Q124.

**16 May 2023**

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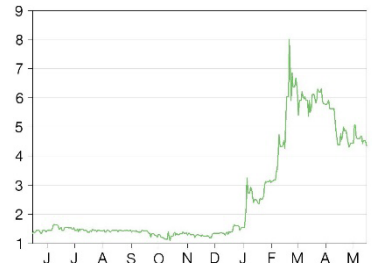
|---|---|
| **Price** | **CHF4.35** |
| **Market cap** | **CHF78m** |
| | €1.03/CHF |
| Net debt (€m) at end December 2022 | 22.4 |
| Shares in issue | 17.8m |
| Free float | 99% |
| Code | NWRN |
| Primary exchange | SIX SWISS Exchange |
| Secondary exchange | N/A |

### Share price performance




### Business description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease is sold in Europe, Japan and the United States. Evenamide, a novel schizophrenia add-on therapy, is involved in a Phase III trial programme targeting schizophrenia.

### Analysts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